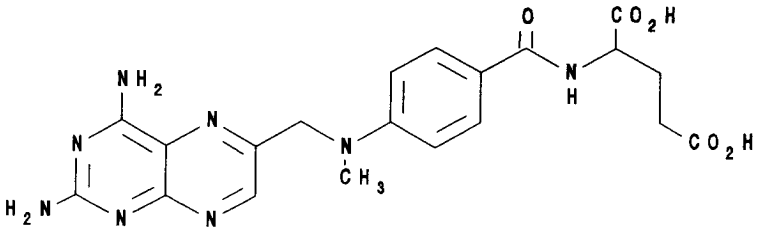
METHOTREXATE

NSC - 740

The following information applies to the investigational dosage forms of methotrexate. For information regarding the commercially available dosage form, consult the package inserts provided by the commercial suppliers.



Chemical Name: N-[4-[[(2,4-diamino-6-pteridinyl)-methyl]methylamino]benzoyl]glutamic acid, L-

Other Names: MTX, Amethopterin, 4-amino-10-methyl-folic acid, Mexate®, Folex®, Rheumatrex®, Methotrexate (USAN)

CAS Registry Number: 59-05-2

Molecular Formula: $C_{20}H_{22}N_8O_5$ **M.W.:** 454.5

How Supplied: For injection, 1.0 gm, vial: supplied as a yellow lyophilized powder of the sodium salt of methotrexate in 30 mL amber vials.

Solution Preparation: When constituted with 19.4 mL of Sterile Water for Injection, USP, each milliliter contains 50 mg of methotrexate as the sodium salt. The pH of the constituted solution is 7.8-8.8.

The 1.0 gm/vial may also be constituted with 0.9% Sodium Chloride Injection, USP, 5% Dextrose Injection, USP, or 5% Dextrose in 0.9% Sodium Chloride Injection, USP.

Storage: Store the intact vials at room temperature.

Stability: Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for 5 years at room temperature (22-25 °C). Intact vials are stable for at least one year at elevated temperature (50 °C).

Constitution of the vials as recommended results in a clear, yellow solution which is chemically stable for at least 7 days at room temperature (22-25 °C).

Further dilution of the constituted solutions with up to 500 mL of 5% Dextrose Injection, USP, 0.9% Sodium Chloride Injection, USP, or 5% Dextrose in 0.9% Sodium Chloride Injection, USP, does not alter solution stability.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous